



MAY - 5 2010

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Washington, DC 20005

In Re: Patent Term Extension
Application for
U.S. Patent No. 6,034,239

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 6,034,239, which claims the human drug product ROZEREM® (ramelteon), a pharmaceutical composition comprising ROZEREM® (ramelteon), a method of using ROZEREM® (ramelteon) and a process for preparing ROZEREM® (ramelteon) is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 868 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 868 days.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of June 19, 2006 (71 Fed. Reg. 35274), would be 1,134 days. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,920 \text{ days} - 260 \text{ days}) + 304 \text{ days} \\ &= 1,134 \text{ days (3.1 years)}\end{aligned}$$

Since the regulatory review period began June 22, 1999, before the patent issued (March 7, 2000), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From June 22, 1999, to and including March 7, 2000, is 260 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,134 days, would extend the patent from March 6, 2017 to April 13, 2020, which is beyond the 14-year limit

(the approval date is July 22, 2005, thus, the 14 year limit is July 22, 2019). The period of extension is thus limited to 868 days, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, March 6, 2017, to and including July 22, 2019, or 868 days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	6,034,239
Granted:	March 7, 2000
Original Expiration Date ¹ :	March 6, 2017
Applicant:	Shigenori Ohkawa et al.
Owner of Record:	Takeda Pharmaceutical Company, Limited
Title:	Tricyclic Compounds, Their Production and Use
Product Trade Name:	ROZEREM® (ramelteon)
Term Extended:	868 days
Expiration Date of Extension:	July 22, 2019

¹Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE By FAX: (571) 273-7755
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.



Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: ROZEREM® (ramelteon)
Docket No.: 2006E-0040

Attention: Beverly Friedman